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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: E. de Juan, et al.

U.S.S.N.: 09/904,201 Art Unit: 3738

FILED: July 11, 2001 Examiner: D. Demille

FOR: INJECTABLE BAG INTROCULAR LENS SYSTEM, INSERTING DEVICE FOR USE THEREWITH, METHOD FOR INSERING AN INJECTABLE BAG INTRAOCULAR LENS WITHINA HUMAN EYE, METHODS FOR TREATING APHAKIA AND SYSTEMS KITS

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CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on 4/1/03.

By: Bmarino
Beth-Ann Marino

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Commissioner of Patents
Washington, D.C. 20231

Sir:

RESPONSE TO OFFICE ACTION

The following is in response to the Office Action mailed October 7, 2002, in the above referenced application.

IN THE SPECIFICATION:

Page 2 line 7 - page 3, line 3:

As a result of these limitations, the treatment of cataracts has developed to include the implantation of an artificial lens, typically called an intraocular lens, in the eye to mimic the function of the original natural lens. With implanted intraocular lenses, there is little or no magnification or distortion. Also, there is no need to remove the intraocular lens from the eye or otherwise handle the lens. Generally, intraocular lenses provide good visual acuity at all times, even at night.

Intraocular lenses have definite advantages in terms of vision and convenience over the other methods of aphakic correction. Intraocular lens implantation surgery, however, is more traumatic than simple cataract extraction alone. The additional handling of the cornea and manipulation inside the anterior chamber during lens implantation add to the amount of trauma to the eye. Extreme care must be exercise to limit trauma to the cornea, structures of the anterior chamber, and other structures. In this microfine surgery uncommon agility on the part of even a skilled surgeon often is required. Space limitations in the eye, the required size of the lens once implanted, and considerable manipulations of the lenses during implantation by the surgeon can result in traumatic damage to the corneal endothelium and very often rupture of the posterior capsule by the novice. Damage to the corneal endothelium and rupture of the posterior capsule are complications considered serious.

a1

Initially, the intraocular lens was a relatively rigid lens requiring a 7-8 mm incision to be made in the conjunctiva and sclera just outside the cornea so that the patient's lens can be removed and replaced with an implant intraocular lens. Incision length is dictated more by the size of the intraocular lens to be implanted than by the requirement of removing the patient's natural lens. For example, since the development of the phacoemulsification technique, the patient's natural lens can be removed using an ultrasonic instrument that requires a corneal incision of about 2-3 mm which is much smaller than is needed to insert a rigid intraocular lens.

Page 4, lines 18-32:

a2

It thus would be desirable to provide a new and novel intraocular lens system as well as related devices and intraocular lens, so as to minimize haptic breakage and concerns with lens manipulation within the lens capsule. It would be particularly desirable to provide such systems, devices, lens and methods related thereto whereby such insertion can be achieved while using minimally sized incisions as in comparison to that for prior art techniques and lens. It also would be desirable to provide such a lens that provides a mechanism for selectively adjusting the refractive power of the lens by means of regulating the material being injected. It also would be yet more

desirable to provide such a lens whereby the refractive power can be adjusted following implantation at a later time during the life of the patient to compensate for changing conditions of the eye. Such lens, insertion devices and systems preferably would be simple in construction than prior art devices, lens and systems and such methods would not be unduly complex as compared to prior art methods.

Page 9, lines 16-27:

The second position of the plunger member 130 generally corresponds to a fully extended flexible bag position, the condition of the flexible bag 142 that is established so the bag can be inflated the desired amount by the injection of the medium 150 therein via the plunger member port(s) 134. The plunger member 130 is moved from the first to the second position by any of a number of mechanisms known to those skilled in the art which can cause the plunger member to be moved back and forth between the first and second positions including mechanisms or devices that are mechanically or fluidly coupled to the plunger member to cause such motion and which are hand-operated or motor operated. In an exemplary embodiment, a motorized screw-drive type of assembly provides the motive force for so moving the plunger member.

IN THE CLAIMS:

Please amend claims 1, 2, 7 and 9 to read as follows:

1. An intraocular lens system comprising an insertion and injection device and a deflated lens member having an interior;

wherein the insertion and injection device includes:

a moveable member having a outlet port provided therein,

an outer member in which is disposed the moveable member,

wherein the deflated lens member is mounted about and to an end of the moveable member such that the deflated lens member is sealingly engaged with a portion of the moveable member so that the interior of the deflated lens member forms a compartment,